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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/046,289      | 01/16/2002  | Henriette Gourdeau   | PHARMA 100 D1       | 1982             |

24999 7590 05/23/2003

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| EXAMINER |
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GOLDBERG, JEROME D

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/046,289

Applicant(s)

GOURDEAU ET AL.

Examiner

Jerome D Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-62 is/are pending in the application.
- 4a) Of the above claim(s) 14-18, 22-24, 27-31, 38-45, 47, 49 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13, 19-21, 25, 26 and 28-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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Claims 11-63 are in this application but claim 12 is missing. The claims are being renumbered as 11-62.

Claims 14-18, 22-24, 27-31, 38-45, 47, 49 and 57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Applicants' remarks are noted and the examination of the claims is modified in that daunorubicin will be examined with the doxorubicin since these compounds are classified together in class 514, subclass 34. The other chemotherapeutic agents such as <sup>in</sup>carboplatin and <sup>in</sup>vinorelbine <sup>are</sup> classified in class 514, subclass 283 while cyclophosphamide <sup>is</sup> classified in class 514, subclass 110. Clearly the extra searching would be a burden on the examiner. Therefore, the restriction requirement herein cleared proper and made final.

Applicant is advised that should claim 35 be found allowable, claim 57 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims are being examined as they read on the elected invention of R-L-OddC with doxorubicin or daunorubicin.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-13, 19-21, 25, 26, 32-37, 46, 48, 50-56 and 58-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Chu et al. WO 9607413 A1 publication having an effective date of March 14, 1996.

The instant application has an effective date of March 29, 1999. The Chu et al. publication teaches applicants' R-L- configuration of the L-odd C in claims 1 and 2 on page 40 (note line 1 "B-L- enantiomer") "can be administered in combination... with anti-tumor pharmaceutical agents" (page 7, lines 22-24) including daunorubicin or doxorubicin (page 8, lines 5 and 6) for treating Leukemia (see page 47, claim 12 and table 2 page 35). The Chu et al. publication on page 27, line 21 teaches a "5 to 500mg

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of active ingredients per unit dosage". The publication does not set forth the elected combination together per se.

However, one skilled in this art would find ample motivation from the prior art supra to combine the well known anticancer agents for their additive effect for treating Leukemia.(In re Sussman, 1943 c.d 518). The showing on page 22 of the specification is noted. The results of the mixture produce a 100% survival time while the doxorubicin alone at 2mg/kg is 50% and the R-L-OddC alone at 1mg/kg is 55%. This is not seen to be greater than the addition of ingredient alone. Clearly, more data is<sup>n</sup> needed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Goldberg/tgd  
May 13, 2003

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke ending in a sharp upward hook.

**JEROME D. GOLDBERG**  
**PRIMARY EXAMINER**